

### REMARKS

Prior to entry of the present amendment, claims 1-14 are pending. Claims 1, 6-9, 13, and 14 are rejected under 35 U.S.C. § 103(a), claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, and claims 9, 13, and 14 are rejected under 35 U.S.C. § 112, second paragraph. Applicants address each basis for rejection as follows.

#### Claim amendments

Claims 1 and 10 have been amended to incorporate features of original claim 2 (5'-AGA<sub>5</sub> 6C-3'), claim 3 (silent mutation), claim 5 (human CFTR), and claim 7 (Sendai virus). Claim 8 has been amended to properly depend from amended claim 1. Original claims 2-7, 9, and 11-14 have been canceled.

No new matter has been added by the present amendments. Applicants reserve the right to pursue any canceled subject matter in this or in a continuing application.

#### Rejection under 35 U.S.C. § 103

Claims 1, 6-9, and 13-14 are rejected under 35 U.S.C. § 103(a) as unpatentable over WO 01/32898 (Yonemitsu et al.) in view of U.S. Patent No. 5,250,846 (Collins et al.). Claims 1, 6-9, and 13-14 are further rejected under 35 U.S.C. 103(a) as unpatentable over Yonemitsu et al. in view of U.S. Patent No. 6,468,793 (Teem).

Applicants have amended independent claims 1 and 10 to include the features of original claims 2, 3, and 5, which were not included in the present obviousness rejections. Applicants submit that the claims as amended are free of the present rejection under 35 U.S.C. § 103. This basis for rejection may be withdrawn.

#### Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph. The Office states:

[T]he specification, while being enabling for a recombinant Sendai virus comprising a nucleotide sequence whose sense strand encodes human CFTR,

where the human CFTR has been altered at the 5'-AGA<sub>5-6</sub>C-3' sequence to lower the sequence identity with the E sequence of the Sendai virus, and wherein the alteration does not affect the amino acid sequence of the encoded human CFTR, and for methods of producing said recombinant Sendai virus comprising 1) altering one or more 5'-AGA<sub>5-6</sub>C-3' sequences present in the human CFTR sequence to a different sequence(s) in order to lower the sequence identity to the Sendai virus E sequence and reduce the mutation frequency of the CFTR sequence, wherein the alteration does not affect the amino acid sequence of the encoded human CFTR, 2) preparing a DNA encoding the genome of the Sendai virus into which the altered CFTR sequence has been inserted, and 3) reconstituting the minus-strand RNA Sendai virus by transcribing the DNA, does not reasonably provide enablement for methods of making a recombinant Sendai virus or the Sendai virus itself as claimed where the virus comprises any foreign gene with any alteration of a sequence in common with the E sequence of the Sendai virus.

(Pages 7-8 of the Office Action, emphasis added)

In short, the Office indicates that the specification is enabling for a "Sendai virus" including a "human CFTR", a "5'-AGA<sub>5-6</sub>C-3'" sequence, and a "silent mutation." Solely to expedite prosecution, Applicants have amended independent claims 1 and 10 to incorporate these features. Applicants submit that the claims as amended are directed to subject matter that the Office has indicated to be enabled by the specification. The rejection for lack of enablement may be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 9 and 13-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 9 and 13-14 have been cancelled and, therefore, this basis for rejection is moot.

CONCLUSION

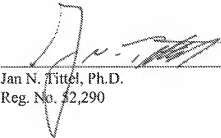
Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

Enclosed are a Petition to extend the period for replying to the Office Action for one month, to and including November 9, 2009, and an authorization to apply the required extension fee to Deposit Account No. 03-2095

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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